

STATEMENT OF SUBSTANCE OF THE INTERVIEW

As an initial matter, Applicants would like to thank the Examiner, Katherine Zalasky, and the Examiner's Supervisor Vickie Kim, for the courtesy of a telephone interview extended to Applicants' Representative, Mr. Enoch E. Peavey, on May 11, 2010. In particular, Applicants' Representative discussed differences between the presently claimed invention and the device of FUKASAWA. No agreement was reached.

REMARKS/ARGUMENTS

Initially, Applicants would like to express appreciation to the Examiner for the detailed Official Action provided.

Upon entry of the above amendments, claims 1 and 15 will have been amended, claim 14 will have been canceled without prejudice or disclaimer to the subject matter contained therein, and claim 20 will have been added. Claims 1, 13 and 15-20 are currently pending. Applicants respectfully request reconsideration of the outstanding rejections, and allowance of all the claims pending in the present application.

Listing of the Rejections under 35 U.S.C. 102 and 103

In the Official Action, the Examiner rejected claims 1 and 13 under 35 U.S.C. 102(b) as being anticipated by FUKASAWA et al. (EP 0306613);

the Examiner rejected claims 14-17 under 35 U.S.C. 103(a) as being unpatentable over FUKASAWA;

the Examiner rejected claims 18 and 19 under 35 U.S.C. 103(a) as being unpatentable over FUKASAWA in view of KANNO et al. (U.S. Patent No. 4,201,673); and

the Examiner rejected claim 1 under 35 U.S.C. § 103(a) as being unpatentable over JP 44-5526.

Without acquiescing to the propriety of the Examiner's rejections, Applicants submit that claim 1 has been amended solely in order to expedite prosecution of the presently claimed invention.

In this regard, Applicants note that none of the applied prior art, alone or in any properly reasoned combination, discloses at least the combination of features recited in independent claim 1.

In particular, amended claim 1 generally sets forth a hollow fiber membrane type fluid treatment device including, inter alia, a housing head portion which is connected with one end of the housing body portion and has a resin layer where the hollow fiber membrane bundle is fixed by using a resin composition, and a connection port which serves as a treatment liquid inlet; a housing head portion which is connected with the other end of the housing body portion and has a resin layer where the hollow fiber membrane bundle is fixed by using a resin composition, and a connection port which serves as a treatment liquid outlet; header caps attached to the housing head portions and having respective treatment target liquid connection ports; and an inner surface of a body portion of the tubular housing at the side of a treatment liquid inlet comprises a body straight portion and an end tapered portion which increases in diameter toward the end face of the housing body portion, and the hollow fiber membranes are arranged so that a distance between the hollow fiber membranes is gradually increased toward the end face on the treatment liquid inlet side along a taper of a tapered portion of the inner surface of the housing body portion, and opening ends of the hollow fiber membrane bundle being fixed to an inside of the housing by the resin layers, and the opening ends of the hollow fiber membrane bundle facing the respective treatment target liquid connection ports such that a liquid to be treated flows within the hollow fiber membranes, and the treatment liquid inlet and treatment liquid outlet being provided at a circumference of the hollow fiber membrane bundle such that a treatment liquid flows outside of the hollow fiber membranes, and wherein an angle formed by a centerline of the inner surface of the housing body portion and an inner surface of the end tapered portion is

greater than 0° and smaller than an angle defined by $\tan^{-1}\{1/2 \cdot (d1-d4)/L4\}$ (where, d1 is the diameter of the hollow fiber membrane bundle at an end face of the resin layer, d4 is an inner diameter of the straight portion or minimum diameter portion of the body portion, and L4 is the length (one side) of the end tapered portion which increases in diameter toward the end face of the housing body portion).

Discussion of FUKASAWA

In setting forth the rejection of claim 14, the Examiner acknowledges that FUKASAWA *does not* disclose the presently claimed angle formed by a centerline of the inner surface of the housing body portion and an inner surface of the end tapered portion being greater than 0° and smaller than an angle defined by $\tan^{-1}\{1/2 \cdot (d1-d4)/L4\}$. (see page 6 of the Official Action).

Nevertheless, the Examiner asserts that the precise angle is considered to be a result effective variable and, without showing unexpected results, is considered to be a matter of optimization. (see page 6 of the Official Action).

Contrary to the Examiner's assertions, Applicants submit that the disclosure of the purported tapered surface in FUKUSAWA does not make the presently claimed range a matter of obvious optimization.

In this regard, Applicants submit that the present Disclosure is clear in explaining that if the angle θ formed by the centerline of the inner surface of the housing body portion and the inner surface of the end tapered portion is not more than 0° , the dialysate may make a serious short-path, whereby the removal performance is significantly decreased. Further, if the angle θ is greater than $\tan^{-1}\{1/2 \cdot (d1-d4)/L4\}$, a space is formed between the hollow fiber membrane bundle and the end tapered portion so that the dialysate makes a short-path through the space,

whereby the removal performance is significantly decreased (see the first full paragraph on page 20 of the present Disclosure).

Accordingly, Applicants submit that the features of the presently claimed invention has at least an advantage over the conventional art in that a short-path does not occur; and therefore, a significant decrease in the removal performance can be prevented (see the first full paragraph on page 20 of the present Disclosure).

Additionally, Applicants submits that there is nothing in the disclosure of FUKASAWA that can reasonably be considered to contemplate or suggest a relationship between selecting an upper limit of the angle (i.e., $\tan^{-1}\{1/2 \cdot (d1-d4)/L4\}$) based upon the diameter of the hollow fiber membrane bundle, an inner diameter of the straight portion, and the length (one side) of the end tapered portion.

Further, as a result of the presently claimed features, Applicants submit that the substance removal performance is significantly increased, and the variation in the substance removal performance is little, and occurrence of leakage due to breakage of the hollow fiber membrane is significantly reduced depending on the diameter-expanding portion. Therefore, the hollow fiber membrane type fluid treatment device of the present invention may be suitably used as a hemodialyzer, endotoxin cut filter, or water filtration device in various fields such as a medical treatment field, food field, and industrial field (see paragraph on page 33 of the present Disclosure).

Furthermore as shown in Table 2, in non-limiting examples 6 to 9 the urea clearance and B12 clearance showed very high values in comparison to the conventional art (e.g., comparative example 3). Moreover, the standard deviations σ of the urea clearance and the vitamin B12 clearance in Examples 6 to 9 are small in comparison with the conventional art (e.g.,

comparative example 3). This suggests that the variation in the dialysate flow between the prototype body fluid treatment devices of the examples is small to exhibit excellent properties from the viewpoint product quality control (see lines 5-26 in page 32 of the present Disclosure).

Thus, Applicants submit that FUKASAWA, alone or in any properly reasoned combination, fails to disclose at least the presently claimed angle formed by a centerline of the inner surface of the housing body portion and an inner surface of the end tapered portion is greater than 0° and smaller than an angle defined by $\tan^{-1}\{1/2 \cdot (d1-d4)/L4\}$ (where, $d1$ is the diameter of the hollow fiber membrane bundle at an end face of the resin layer, $d4$ is an inner diameter of the straight portion or minimum diameter portion of the body portion, and $L4$ is the length (one side) of the end tapered portion which increases in diameter toward the end face of the housing body portion), as recited in claim 1.

Furthermore, in setting forth the rejection of claim 1, the Examiner asserts that FUKASAWA discloses the presently claimed body straight portion which the Examiner considers to be straight portions on the inner surface near ports 27 and 28. (see the last bullet on page 2 of the Official Action). Further, in rejecting claim 16 the Examiner asserts that the ratio of the length to the body straight portion to the total length of the tapered portion is merely an obvious change in size and shape. (see page 7 of the Official Action beginning at line 5).

Contrary to the Examiner's assertions, Applicants submit that, if the Examiner is to be consistent with the Official Action's interpretation of FUKASAWA, then the straight portions on the inner surface of caps near ports 27 and 28 are part of the housing head portions 29 and 20 and *not* the housing body portion. (see Figure 3 in FUKASAWA).

In this regard, Applicants submit that the purported body portion in FUKASAWA is clearly comprised of two tapered halves that meet at a center of the purported body portion (see Figure 3 in FUKASAWA).

Thus, Applicant submits that FUKASAWA also fails to disclose the presently claimed surface of a body portion of the tubular housing at the side of a treatment liquid inlet comprises a body straight portion and an end tapered portion which increases in diameter toward the end face of the housing body portion, as recited in claim 1; much less, a ratio of the length of the body straight portion to the total length of the end tapered portion is 0.7 to 20, and a ratio of the inner diameter of the end tapered portion on the end face side to the inner diameter of the body straight portion is more than 1 and not more than 3, as recited in claim 16.

Furthermore, Applicants submit that the presently claimed invention clearly sets forth the advantages associated with the aforementioned feature; and therefore, the aforementioned feature is *not* merely an obvious change in size or shape as the Examiner suggests.

In particular, Applicants submit that the presently claimed ratio $((L2-L4)/L4)$ of the length of the body straight portion to the length of the end tapered portion has at least an advantage over the applied prior art in that it prevents a short-path from occurring; and as a result, prevents the removal performance from being insufficient. (see lines 10-15 in page 21 of the present Disclosure).

Discussion of JP 44-5526

Further, Applicants submit that the Examiner apparently acknowledges that JP 44-5526 does not disclose or suggests the features recited in claim 14.

Accordingly, Applicants submit that, because the features recited in claim 14 have been generally incorporated into claim 1, the rejection of claim 1 (as being unpatentable over JP 44-5526) is improper and should be withdrawn.

Additionally, for reasons discussed *supra*, Applicants submit that JP 44-5526 also *cannot* reasonably be considered to contemplate or suggest the presently claimed angle formed by a centerline of the inner surface of the housing body portion and an inner surface of the end tapered portion being greater than 0° and smaller than an angle defined by $\tan^{-1}\{1/2 \cdot (d1-d4)/L4\}$ (where, d1 is the diameter of the hollow fiber membrane bundle at an end face of the resin layer, d4 is an inner diameter of the straight portion or minimum diameter portion of the body portion, and L4 is the length (one side) of the end tapered portion which increases in diameter toward the end face of the housing body portion), as set forth in claim 1.

Generally

Accordingly, Applicants submit that the rejections of claims 1 and 13-19 under 35 U.S.C. §§ 102 and 103 are improper and should be withdrawn.

In view of the arguments herein, Applicants submit that independent claim 1 is in condition for allowance. With regard to dependent claims 13 and 15-20, Applicants assert that these claims are allowable on their own merit, as well as because they depend from independent claim 1 which Applicants have shown to be allowable.

Thus, it is respectfully submitted that all of the claims in the present application are clearly patentable over the references cited by the Examiner, either alone or in combination, and an indication to such effect is respectfully requested, in due course.

SUMMARY

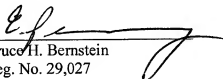
Applicants submit that the present application is in condition for allowance, and respectfully requests an indication to that effect. Applicants have argued the allowability of the claims and pointed out deficiencies of the applied references. Accordingly, reconsideration of the outstanding Official Action and allowance of the present application and all the claims therein are respectfully requested and is now believed to be appropriate.

Applicants submit that this amendment is being made to advance prosecution of the application to allowance and should not be considered as surrendering equivalents of the territory between the claims prior to the present amendment and the amended claims. Further, no acquiescence as to the propriety of the Examiner's rejection is made by the present amendment. All other amendments to the claims which have been made in this amendment, and which have not been specifically noted to overcome a rejection based upon the prior art, should be considered to have been made for a purpose unrelated to patentability, and no estoppel should be deemed to attach thereto.

P28510.A05

Should the Examiner have any questions or comments regarding the present response or this application, the Examiner is respectfully invited to contact the undersigned at the below listed number.

Respectfully submitted,
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